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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,397	01/31/2001	Theresa A. Hadlock	00786-446001	3080

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EXAMINER

JACKSON, GARY

ART UNIT PAPER NUMBER

3731

DATE MAILED: 06/25/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

**Office Action Summary**

Application No.

09/774,397

Applicant(s)

HADLOCK ET AL.

Examiner

Gary Jackson

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-43, 45-49 and 55-59 is/are rejected.
- 7) ☒ Claim(s) 5, 44 and 50-54 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

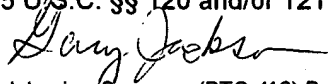
- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:



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### **DETAILED ACTION**

This action is a response to applicants' amendment filed March 24, 2003.

In view of said amendment, the indicated allowability of the claims has been withdrawn and new grounds of rejection is set forth.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6 and 7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Stensaas et al (US Patent 4,778,467). See figure 7A of the reference.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-3, 8-18, 40-43, 45-46 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butler et al in view of Stensaas et al, Goosen et al (US Patent 4,806,355) and Hadlock et al publication "A Polymer Foam Conduit Seed with Schwann Cells Promotes Guided Peripheral Nerve Regeneration". Again, Butler discloses a method for regenerating nerves with use of a cell-encapsulating device. Stensaas et al teaches the use of a rolled device for regenerating nerves. Hadlock et al discloses providing cells suspended in nerve regeneration conduit. Goosen suggest encapsulating cells.

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It would have been within the purview of one having ordinary skill in the to provide Butler with the spiral roll device of Stensaas et al so as to wrap the nerve ends for tighter grip rather than inserting the ends into a grip. See figure 7A of Stensaas et al. In the alternative, it would have been obvious to one having ordinary skill in the art to provide Stensaas et al with an encapsulated layer of cells to promote nerve regeneration.

Claims 19-39, 47-49 and 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butler, Stensaas, Goosen and Hadlock in further in view of Dionne et al (US Patent 5,773,286). The latter reference suggests encapsulating neurotrophic agents in separate spheres. It would have been obvious to one having ordinary skill in the art to provide Butler, Stensaas and Hadlock combination with encapsulated neurotrophic agents to promote nerve growth.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 58 is indefinite because it is not clear and does not clearly point out any steps for regenerating nerves.

***Allowable Subject Matter***

Claims 5, 44 and 50-54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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*Response to Arguments*

Applicant's arguments filed March 24, 2003 have been fully considered but they are not persuasive. The examiner respectfully disagrees with applicants' argument that Stensaas does not disclose a method that includes a rolling a support around nerve ends. See figure 7 and column 16, line 54 to column 18.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary Jackson whose telephone number is (703) 308-4302. The examiner can normally be reached on Mon.-Thurs. 7:30 am to 6:00 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 308-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Gary Jackson  
Primary Examiner  
Art Unit 3731

GJ  
June 16, 2003